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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,612	01/05/2004	T. Erik Mirkov	017575.0774 (TAMUS 1910)	2393
5073	7590	07/18/2006	EXAMINER MCELWAIN, ELIZABETH F	
BAKER BOTTS L.L.P. 2001 ROSS AVENUE SUITE 600 DALLAS, TX 75201-2980			ART UNIT 1638	

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/751,612

Applicant(s)

MIRKOV ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 16-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2-14 and 16-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Prosecution Application***

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 27, 2006 has been entered, and the after final amendment submitted March 10, 2006 has been entered.

Claims 2, 3, 5, 7, 11, 17-19, 26 and 27 are currently amended.

Claims 1-14 and 16-34 are pending and are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

1. Claims 2-14 and 16-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the last office action.
2. Applicants' arguments filed March 10, 2006 have been fully considered but they are not persuasive. Applicants assert that the amendment of the claims to recite a nucleic acid having a sequence 98% homologous to SEQ ID NO: 1 reduces the number of species in the genus and

Art Unit: 1638

there are likely to be conserved promoter regions that would be required in allelic variants and other mutants that are able to function as a promoter. The Examiner maintains that only one sequence has been provided in the form of SEQ ID NO: 1, which has been shown to exhibit the functional activity of having stem-regulated promoter activity. And the specification does not teach what the conserved promoter regions would be required for the sequence to function as a stem-regulated promoter

3. Claims 2-14 and 16-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the promoter having stem-regulated activity of SEQ ID NO: 1, does not reasonably provide enablement for any nucleic acid that is at least 98% identical to SEQ ID NO: 1 having stem regulated activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons set forth in the last office action.

4. Applicants' arguments filed March 10, 2006 have been fully considered but they are not persuasive. Applicants assert that the claims have been amended to recite a nucleic acid having a sequence 98% homologous to SEQ ID NO: 1, and that even though SEQ ID NO: 1 has a large number of bases, it would not be unduly burdensome for one skilled in the art to test variants that are 98% homologous. Applicants further argue that it is well known that certain promoter regions may not be changed without interfering with promoter activity. Therefore those skilled in the art would know not to change those regions, thus limiting the number of variant promoters to be tested.

Art Unit: 1638

5. The Examiner maintains that applicants have provided one example in the form of SEQ ID NO: 1, which is 3016 nucleotides long and has stem-regulated promoter activity. However, applicants are claiming any sequence that is at least 98% identical to SEQ ID NO: 1. Therefore, up to 2% of the nucleotides may be substituted for, hence any of 1 to 60 nucleotides may be varied. With  $3^{3016}$  possible single nucleotide substitutions at any of 1 to 60 nucleotide positions, this is still an enormous number of possible sequences to be tested without any guidance with regard to which nucleotides may be substituted for, while retaining the stem-regulated promoter activity. While a person of skill in the art would know how to test for stem-regulated activity and would know not to modify that TATA and CAT boxes, it would require undue experimentation to identify other sequences having the claimed activity, in view of the unpredictability with regard to required sequence regions in promoters, as stated in the last office action, and given the breadth of the claims, and in view of the level of ordinary skill in the art, which is high.

### ***Conclusion***

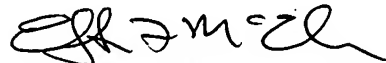
Claim 1 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

Art Unit: 1638

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth F. McElwain, Ph.D.  
Primary Examiner  
Art Unit 1638

EFM